



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,491	08/27/2001	Cecile Chartier	032751-070	3862

7590 07/05/2005

Norman H. Stepno
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. Box 1404
Alexandria, VA 22313-1404

EXAMINER

HILL, MYRON G

ART UNIT PAPER NUMBER

1648

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/938,491

Applicant(s)

CHARTIER ET AL.

Examiner

Myron G. Hill

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This action is in response to the paper filed April 6, 2005.

This action is on claims 24-40.

Rejections Maintained

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 24- 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Applicant points to Example 1C for support of the amendment.

The claims read on preparing a "gutless" adenoviral vector.

Applicant argues that that the support is from at least Example 1C, that the specification is enabled for a vector lacking all or part of E1, E2, E3, and or E4, that the examiner is attempting to limit the claims to Example 1C, that the parts are not in reverse order as asserted by the Examiner, that there is no need to for the first fragment to be a full length Adenovirus genome.

Applicant's arguments have been fully considered and not found persuasive.

The Examiner first looks to where pointed to by Applicant for support for amendments. The Examiner is not limiting Applicant to the method of Example 1C, deletions of all or part of E1, E2, E3, and or E4 are described.

Applicant argues that the claims are supported by the disclosure of "all or part of E1, E2, E3, and or E4". This is not persuasive or commensurate with the claims as now written. The genomic structure of Adenovirus is well known in the art and there are more regions than E1, E2, E3, and E4 in the genome. See Figure 1 of the instant application or a prior art map can be supplied that shows the additional regions beyond all or part of E1, E2, E3, and E4. When even all of E1, E2, E3, and E4 are deleted, substantial virus genome remains.

The comment about reverse order was not to require applicant to recite the fragments literally as disclosed but to point out that the claim refers to the fragments in a different order.

Applicant points to a portion of the specification (page 9, lines 31-32) that states that the first DNA fragment can comprise some or all of the DNA of the parent in the context of the invention. The specification as a whole only refers to deletions of all or part of E1, E2, E3, and or E4 and provides examples of such. The application does not provide support for making gutless vectors and the support pointed out by applicant does not show written description for more than deletions of all or part of E1, E2, E3, and or E4 when the disclosure is considered as a whole.

The rejection is maintained.

Claim 40 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant points to Examples 1d and 1 h as support for the new claim.

The claim reads on a "gutless" adenovirus vector.

Applicant argues that the reasons were discussed above, that the specification is enabled for a vector lacking all or part of E1, E2, E3, and or E4 referring to page 11, lines 9-12, and that Figure 1 shows that E1, E2, E3, and E4 regions compose all the internal sequence of the genome.

Furthermore, Applicant argues that the examiner has the burden of showing why a person of skill in the art would not recognize in applicants' specification disclosure a description of the invention as defined by the claims.

Applicant's arguments have been fully considered and not found persuasive.

The Examiner first looks to where pointed to by Applicant for support for amendments. The Examiner is not limiting Applicant to the method of the examples, deletions of all or part of E1, E2, E3, and or E4 are described.

Applicant argues that the claims are supported by the disclosure of "all or part of E1, E2, E3, and or E4" because this composes all the internal sequence of the genome.

Art Unit: 1648

This is not persuasive. The genomic structure of Adenovirus is well known in the art and there are more regions than E1, E2, E3, and E4 in the genome.

Applicant points to a portion of the specification (page 11, lines 13-37 that concludes by stating the invention can be used for introducing deletions/insertions/mutations "into a particular region of a viral genome". This does not support the claims as written. The specification as a whole only refers to deletions of all or part of E1, E2, E3, and or E4 and provides examples of such. The application does not provide support for making gutless vectors and the support pointed out by applicant does not show written description for more than deletions of all or part of E1, E2, E3, and or E4 when the disclosure is considered as a whole.

The arguments concerning burden and skill in the art is not persuasive. Applicants arguments in this reasoning are in line with enablement and not commensurate with written description. The rejection is not an enablement rejection. The examiner has put forth why the disclosure does not support the claims.

Applicant can point to further parts of the specification that support the claims or can provide evidence that at the time of filing the disclosure as written supports the claims as currently recited.

The rejection is maintained.

Conclusion

No claim is allowed.

Art Unit: 1648

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Myron G. Hill

Patent Examiner

June 23, 2005



ALL R. SALIMI
PRIMARY EXAMINER